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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/719,221

02/16/2001

Doris Hubler

JENA 3

7076

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7590

10/20/2006

EXAMINER

WEBMAN, EDWARD J

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.  
2200 CLARENDON BLVD.  
SUITE 1400  
ARLINGTON, VA 22201

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary  
for Applications  
Under Accelerated Examination**

Application No.

09/719,221

Applicant(s)

HUBLER ET AL.

Examiner

Edward J. Webman

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Since this application has been granted special status under the accelerated examination program,  
NO extensions of time under 37 CFR 1.136(a) will be permitted and a **SHORTENED STATUTORY PERIOD FOR  
REPLY IS SET TO EXPIRE:**

**ONE MONTH OR THIRTY (30) DAYS, WHICHEVER IS LONGER,**  
FROM THE MAILING DATE OF THIS COMMUNICATION – if this is a non-final action or a *Quayle* action.  
(Examiner: For **FINAL** actions, please use PTOL-326.)

The objective of the accelerated examination program is to complete the examination of an application within twelve months from the filing date of the application. Any reply must be filed electronically via EFS-Web so that the papers will be expeditiously processed and considered. If the reply is not filed electronically via EFS-Web, the final disposition of the application may occur later than twelve months from the filing of the application.

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 August 2006.  
2) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 3) ☒ Claim(s) 12, 15, 20, 32, 33 and 38-60 is/are pending in the application.  
3a) Of the above claim(s) 43, 49 and 50 is/are withdrawn from consideration.  
4) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
5) ☒ Claim(s) 12, 15, 20, 33, 38-42 and 44-48, 51-60 is/are rejected.  
6) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
7) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 8) ☐ The specification is objected to by the Examiner.  
9) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
10) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 11) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_.

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Claims 12, 15, 16, 20, 32, 33, 35, 38-42, 44-46, 51-60 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Prophylaxis is synonymous with prevention. Applicants merely show inhibition, and that only under defined *in vitro* conditions, rather than prevention. Further, nowhere in the specification do applicants define what they experimentally consider as prevention.

Claims 12, 15, 16, 20, 32, 33, 35, 38-42, 44-46, 51-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Because applicants invention does not possess utility regarding prevention, applicants are not enabled for the claimed method of use.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33, 45, 39-42, 46, 53-54, 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hesch et al (US 5,795,883) in view of Neri (US 3,423,507) .

Hesch et al disclose that it is well known in the art that androgens such as testosterone are useful in methods of treating androgen deficiency in man (column 1,

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lines 10-16). Such a deficiency is known to cause benign enlargements of the prostate (column 1, lines 46-54). Testosterone propionate is specified (column 1 line 13).

However, Hesch et al do not disclose the addition of a gestagen.

Neri teaches cyproterone for treating benign prostate hyperplasia (title, abstract).

Tablets are disclosed (column 3 line 12 et seq.)

It would have been obvious to one of ordinary skill to add cyproterone to the androgen deficiency treatment disclosed by Hesch et al to achieve the beneficial effect of treating the accompanying enlargement of the prostate in view of Neri. Given that Neri teaches a tablet, it would be an obvious expedient to deliver both testosterone and cyproterone in such a vehicle.

As to the claimed ranges of androgen and gestagen dosages, it is within the skill of the art to select optimal parameters such as ratios, ranges of doses or weight percents of components in order to achieve a beneficial effect. See In re Boesch, 205 USPQ 215 (CCPA 1980). Therefore, the ratios, ranges of doses or weight percents instantly claimed are not considered critical absent evidence showing unexpected and superior results.

Applicants argue that neither reference teaches prophylaxis. However, in light of the rejections under 35 USC 101 and 35 USC 112, the examiner it appears interprets "prophylaxis" to mean "treatment", in which case the rejection under 35 USC remains apt.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500